K082104

SEP - 2 2008

GE Healthcare

3000 N. Grandview Blvd. W-706
Waukesha, WI 53188

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Submitter:

Name: GE Medical Systems, LLC (GE Healthcare)
Address: 3000 N. Grandview Blvd., W-706
Waukesha, WI 53188

Contact: Steven Kachelmeyer
Pre-Market Regulatory Affairs Program Manager
Tel: 262-548-2432, Fax: 262-997-1080
e-mail: steven.kachelmeyer@med.ge.com

Date Prepared: July 18, 2008

PRODUCT IDENTIFICATION

Name: GE LightSpeed RT^{16} / LightSpeed Xtra V2
(Also known as LightSpeed RT^{16} /LightSpeed Xtra CT Scanner System)

Classification Name: Computed Tomography X-ray System
21CFR892.1750, 90-JAK

Manufacturer: GE Hangwei Medical Systems Co. Ltd.
No 1 Young Change North Rd
Beijing Economic and Technology Development Zone
Beijing, China 100176

Future Production may also be accomplished at one of our other registered CT Manufacturing facilities.

Distributor: Same as Manufacturer

Marketed Devices: The GE LightSpeed RT^{16} / LightSpeed Xtra V2 (aka LightSpeed RT^{16} /LightSpeed Xtra CT) is of comparable type and substantially equivalent to GE's currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards and have similar intended uses, such as the previous LightSpeed Xtra CT Scanner.

Predicate Device(s):

GE LightSpeed Xtra CT Scanner System (K060052)

DEVICE DESCRIPTION

The GE LightSpeed RT16 / LightSpeed Xtra V2 (aka LightSpeed RT16 /LightSpeed Xtra CT) CT Scanner System is composed of a gantry, patient table, operator console, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.

The system generates images through the computer reconstruction of data acquired at different angles and planes of the rotating gantry. The gantry can rotate at up to 0.5 seconds (at full) per rotation, and can acquire up to 16 slices of data per rotation with a maximum total coverage of 20mm in the axial direction. The system can be operated in Axial, Cine, Helical, Fluoro and Gated acquisition modes.

The GE LightSpeed RT16 / LightSpeed Xtra V2 CT Scanner System is designed to be a head and whole body CT scanner incorporating the same basic fundamental operating principles and similar Indications for Use. Materials and construction are equivalent to our existing marketed products, which are compliant with UL 60601-1, IEC 60601-1 and associated collateral and particular standards, and 21CFR Subchapter J.

Indications for Use:

The GE LightSpeed RT16 / LightSpeed Xtra V2 Computed Tomography System (aka GE LightSpeed RT16 / LightSpeed Xtra) is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), and Gated acquisitions for all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The GE LightSpeed RT16 / LightSpeed Xtra V2 Computed Tomography System (aka GE LightSpeed RT16 / LightSpeed Xtra) is indicated for head, whole body, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

The system is capable of assisting with minimally invasive procedures such as biopsy and ablation of tumors and pathology. The system allows imaging of Bariatrics patients, up to and including the morbidly obese population (BMI > 40).

Comparison with Predicate:

The GE LightSpeed RT16 / LightSpeed Xtra V2 CT Scanner System is developed from the hardware platform of our LightSpeed Xtra system (K060052). The GE LightSpeed RT16 / LightSpeed Xtra V2 involves changes from the LightSpeed Xtra system to add new application features that involve changes in hardware, application software, and firmware. The GE LightSpeed RT16 / LightSpeed Xtra V2 CT Scanner System uses virtually the same materials and identical operating principle as our existing marketed product, LightSpeed Xtra, as well as having similar indications for use. We believe the GE LightSpeed RT16 / LightSpeed Xtra V2 Scanner System is of comparable type and substantially equivalent to our currently marketed system listed above and complies with the same or equivalent standards and have the same intended uses.

The GE LightSpeed RT16 / LightSpeed Xtra V2 CT Scanner System will be certified to comply with the X-ray requirements of 21CFR1020.30 and1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards.

Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC).
- Compliance to applicable CDRH 21CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21CFR820.

Conclusions:

The GE LightSpeed RT16 / LightSpeed Xtra V2 CT Scanner System is an evolutionary modification to the LightSpeed 7.1 32/64 slice system (K061817). It does not result in any new potential safety risks and performs as well as or better than devices currently on the market. The GE LightSpeed RT16 / LightSpeed Xtra V2 CT system will be certified to comply with the X-ray requirements of 21CFR 1020.30 and 1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards. GE considers the GE LightSpeed RT16 / LightSpeed Xtra V2 CT Scanner System to be equivalent to other marketed devices with similar indications for use and meeting similar standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

GE Medical Systems, LLC (GE Healthcare)
% Mr. Daniel W. Lehtonen
Senior Staff Engineer – Medical Devices
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K082104
Trade/Device Name: GE LightSpeed RT^{16} / LightSpeed Xtra V2 (aka GE LightSpeed RT^{16} / LightSpeed Xtra) CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 20, 2008
Received: August 21, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082104

Device Name: GE LightSpeed RT16 / LightSpeed Xtra V2 (aka GE LightSpeed RT16 / LightSpeed Xtra) CT Scanner System

Indications for Use:

The GE LightSpeed RT16 / LightSpeed Xtra V2 Computed Tomography System (aka GE LightSpeed RT16 / LightSpeed Xtra) is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), and Gated acquisitions for all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

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When used in the LightSpeed RT16 configuration, the system can acquire CT anatomical images that are clinically useful in the simulation and planning of radiation therapy for the treatment of cancer.

Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082104